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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,942	07/21/2003	Marco Pappagallo	05986/100K504-US1	7691

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
06/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,942	PAPPAGALLO, MARCO	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/25/2008 & 4/7/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed on February 25, 2008 have been received and entered into the application.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Action Summary

The rejection of claims 1-3, 5- 9 and 11 under 35 U.S.C. 102(a) as being anticipated by Geusens et al. (2001) is hereby expressly withdrawn in view of Applicants' persuasive argument.

The rejection of claims 1, 4 and 10 under 35 U.S.C. 103(a) as being unpatentable over Urban et al. (2001) in view of Bader et al. is being maintained for the reasons stated in the previous Office Action.

Upon further consideration, additional rejection has been made in this Office Action.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geusens et al. (2001) of record.

Geusens et al. teach that an 18-year-old boy presented with extreme back pain as the result of multiple vertebral fractures was treated with intermittent intravenous bisphosphonate such as **pamidronate**. (abstract). Geusens et al. teach that intermittent IV infusions of pamidronate were given at dose of 30mg infusion, 300 mg in total over 9 month. (page 390 right-hand column first sentence originated from left-hand column, bottom). The boy progressively recovered from **back pain** and is now, at age 20, fully ambulant. (abstract).

Geusens et al. do not teach the specific chronic spinal mechanical pain as being any back pain lasting more than twelve weeks which is not caused by cancer, or an osteoporotic compression fracture as defined in the specification page 7.

However, it would have been obvious to one of ordinary skill in the art to employ pamidronate for the treatment of any back pain regardless of the cause because the effectiveness of pamidronate in pain management is well taught by Geusens et al. One would have been motivated to employ pamidronate for the treatment of any pain regardless of its cause in order to achieve the beneficial analgesic effect of pamidronate in the patient disclosed by Geusens et al. who progressively recovered from suffering from an extreme back pain with the treatment comprising pamidronate. There is a reasonable expectation of successfully treating any pain particularly back pain

regardless of a cause because pamidronate treatment in the patient disclosed by Genuses recovered from the back pain with administration of pamidronate, therefore, the analgesic effect of pamidronate would be retained and it would be effective of treating pain regardless of the etiology of how the patient conceived pain.

Claims 1-8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urban et al. (2001) in view of Bader et al, both of record.

Urban et al. teach that the bisphosphonate, zoledronate (30mcg/kg, s.c.) produced a significant anti-allodynic effect in rats. (abstract).

Urban et al. do not teach the intravenous administration of zoledronic acid for the treatment of pain.

Bader et al. report that bisphosphonates and their salts including zoledronate has been used as parenteral preparations for intravenous infusion and injection and preferably made available and utilized. (column 1, lines 14-26).

It would have been obvious to one of ordinary skill in the art to employ zoledronic acid for the treatment of pain in intravenous administration because zoledronic acids is well-known to be administered intravenously and preferably made available and utilized in parenteral infusion and injection formulations as taught by Bader et al. One would have been motivate do employ zoledronic acid in preferred parenteral preparations including intravenous injection in order to provide alternative parenteral preparations next to subcutaneous injectable taught by Urban. There would have been a reasonable expectation of successfully administering zoledronic acid intravenously for the treatment

of pain because intravenous infusion and injection formulation of zoledronate are preferably made available to be utilized as reported by Bader et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicant's arguments filed February 25, 2008 have been fully considered but they are not persuasive. Applicant essentially argues that the claims term "chronic spinal mechanical pain" is expressly defined in the specification at page 7 as any back pain lasting more than twelve weeks which is not caused by cancer, or an osteoporotic compression fracture but the Pappagello Declaration states that the patient described in Geusens has osteoporotic vertebral compression fracture. This is not found persuasive because although Geusens discloses the treatment comprising pamidronate for the osteoporotic vertebral compression fracture, it does not change the relevant teaching that pamidronate is useful in the alleviation of back pain. There is a reasonable expectation of treating back pain at any cause because the cause of pain in a subject will not change an analgesic property of pamidronate. Accordingly, it would have been

obvious to one of ordinary skill in the art to employ pamidronate in treating back pain with any cause including non-osteoporotic compression fracture origin and non-cancer origin because pamidronate is effective for the treatment of back pain as taught by Geusens. Applicant argues that Urban and Bader in combination does not disclose or suggest treating "chronic spinal mechanical pain" as expressly defined by the instant specification because Urban is limited to the treatment of bone cancer-induced pain and Bader discloses treating osteoporosis using bisphosphonates. This is not found persuasive because although Urban teaches an employment of zoledronate for treating pain resulted from a bone cancer, it does not change the relevant teaching that zoledronate is effective in treating pain. There is a reasonable expectation of treating back pain at any cause because the etiology of pain in a subject will not change the effectiveness of pamidronate having analgesic effect. Accordingly, it would have been obvious to one of ordinary skill in the art to employ zoledronate in treating pain of any origin because zoledronate is effective for the treatment of pain as taught by Urban. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
June 2, 2008